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Brief Summary

INDICATION
For the treatment of constipation. In patients with a history of chronic constipation, lactulose syrup (Chronulac) therapy increases the number of bowel movements per day and the number of days on which bowel movements occur.

CONTRAINDICATIONS
Since Chronulac contains galactose (less than 2.2 g./15 ml.), it is contraindicated in patients who require a low galactose diet.

WARNINGS
Use in Pregnancy
Studies in laboratory animals (mice, rats, rabbits) have not revealed a teratogenic potential of Chronulac. The safety of Chronulac syrup during pregnancy and its effect on the mother or the fetus have not been evaluated in humans. The physician and patient should understand that the possibility that Chronulac might cause damage to the human fetus cannot be excluded. Chronulac should not be given during pregnancy unless, in the opinion of the physician, the possible benefits outweigh the possible risks.
Use in Nursing Mothers
There are no data on secretion of Chronulac in human milk or effect on the nursing infant.
Use in Children
There is insufficient experience to recommend a dose of Chronulac that is safe and effective for treatment of constipation in children.

PRECAUTIONS
Elderly, debilitated patients who receive Chronulac for more than six months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically. Also, since Chronulac contains galactose (less than 2.2 g./15 ml.) and lactose (less than 1.2 g./15 ml.), it should be used with caution in diabetics.

ADVERSE REACTIONS
Initial dosing may produce flatulence and intestinal cramps, which are usually transient. Excessive dosage can lead to diarrhea. Nausea has been reported.

OVERDOSAGE
There have been no reports of accidental overdosage. In the event of overdosage it is expected that diarrhea and abdominal cramps would be the major symptoms. Medication should be terminated.

DOSAGE AND ADMINISTRATION
The usual dose is 1 to 2 tablespoonfuls (15 to 30 ml., containing 10 g. to 20 g. of lactulose) daily. The dose may be increased to 60 ml. daily if necessary. Twenty-four to 48 hours may be required to produce a normal bowel movement.
Note: Some patients have found that Chronulac may be more acceptable when mixed with fruit juice, water, or milk.

Product Information as of April, 1979
(Package Information amended July, 1979)

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